

REMARKS

Applicants herein respond to the office action mailed April 27, 2000.

Applicants have amended claim 54 in the manner suggested by the examiner, which moots the product of nature and indefiniteness rejections. Claims 37-57 remain pending. The office action is discussed below.

Double Patenting

On page 2 of the office action, the examiner rejected claims 37, 51 and 57 on obviousness-type double patenting grounds. The examiner believes that the subject matter of claims 37, 51 and 57 are obvious over the claims 2 and 10 of U.S. Patent No. 5,833,989, which the examiner considers as pertaining to an SCR 3 polypeptide. Applicants respectfully traverse this rejection.

Applicants note that these type of rejections are intended to prevent an impermissible "prolongation" of the patent term caused by multiple patents possessing claims that are obvious in view of one another. That is, the claimed subject matter must be sufficiently close that issuance of more than one patent would permit a prolonged term for the same inventive concept.

Accordingly, in making an obviousness-type double patenting rejection, the examiner must indicate how the claims of the instant application are sufficiently "obvious" over the other claims so as to result in an impermissible prolongation of

Serial No. 09/142,043

patent term. The claims of the instant application implicate an SCR 3-derived molecule having only 6-23 amino acids. The examiner has not shown how this subject matter is rendered obvious by the claimed subject matter of the '989 patent. Applicants therefore respectfully submit that the examiner has not met the burden of establishing a *prima facie* case, and thus the rejection should be withdrawn.

Enablement

On page 3 of the office action, the examiner maintained the previous enablement rejection. In making this rejection, the examiner has attempted to limit the application to the sequences of SEQ ID NOS. The examiner, however, provides no technical reason for doubting the enabling qualities of the specification and its support of the claims at issue. Applicants respectfully traverse this rejection.

Section 112 mandates that patent applications contain the "manner and process of making and using" the invention. The courts have considered applications in compliance with section 112 where the person of skill in the art can practice the invention without undue experimentation. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986). The test is not whether experimentation is necessary, but whether any experimentation would be undue in view of what type and amount of experimentation is usual in that particular field. *See MPEP*

Serial No. 09/142,043

§ 2164.05(b) (Rev. 1, February 2000). Routine design choices cannot be equated with non-enablement.

The burden to establish an enablement rejection rests with the examiner. *See* MPEP § 2164.04 (Rev. 1, February 2000). As explained by the Federal Circuit in considering the intertwined issues of enablement and utility:

[I]t follows that the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the inventor's asserted utility. * * * Taking these facts – the nature of the invention and the PTO's proffered evidence – into consideration we conclude that one skilled in the art would be without basis to reasonably doubt applicants' asserted utility on its face. The PTO has not satisfied its initial burden. Accordingly, applicants should not be required to substantiate their presumptively correct disclosure to avoid a rejection under the first paragraph of § 112.

In re Brana, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (emphasis added), *citing In re Marzocchi*, 169 USPQ 367, 369-70 (CCPA 1971).

Accordingly, it must be determined whether the examiner has met the burden. First, applicants submit that the examiner has provided no evidence to doubt the broad applicability of the claimed invention, which is sufficient to compel withdrawal of the rejections. Applicants nevertheless explain below why the claims are, in fact, enabled.

The GGRKVF and FELVGEPsiY sequences recited in claims are contained in the sequences set forth in the Examples. At page 22 of the specification, the biological activity of these sequences was demonstrated by way of a sheep erythrocyte hemolysis test. Thus, applicants have shown that the sequences are functional, and therefore the enablement rejection should be withdrawn.

Written Description

On page 3 of the office action, the examiner maintained the previous written description rejection. In making this rejection, the examiner contends that applicants have not shown that they were in possession of the invention. Applicants respectfully traverse this rejection.

The U.S. Patent and Trademark Office published on December 21, 1999 in the Federal Register (64 Fed. Reg. 71427) its revised interim guidelines for written description. First, the guidelines counsel examiners to review the entire specification and then determine whether all subject matter that is essential to the invention is actually recited in the claims. See Guidelines at II(A)(2). Next, the examiners must determine whether the applicant was in possession of all that is claimed. *Id.* at II(A)(3). Possession can be shown by disclosure of structural characteristics, functional characteristics that correlate with structure or combinations thereof. *Id.* at II(A)(3)(a).

On page 4, lines 3-8 of the application, applicants have identified sequences a) and b), at least one of which must be in the recited polypeptide, along with the overall size of the polypeptide. Thus, applicants possessed the structural parameters of the invention of the polypeptides.

Pages 5-9 of the application teach production methodologies useful for making the polypeptides. Polynucleotides encoding the polypeptides also were possessed by applicants simply by turning to codon usage charts for determining trinucleotides that encode a given amino acid. See page 5, lines 9-11 of the specification. Expression vectors containing such polynucleotides are readily available, and can be done according to well-known protocols, such as those of Sambrook. See page 6, lines 1-4 of the specification. Thus, the person of ordinary skill, relying upon the knowledge in the art, would not doubt that applicants possessed the invention as claimed. Accordingly, applicants request withdrawal of the rejection.

Prior Art

On page 3 of the office action, the examiner rejected claims 37, 39 and 51-57 as anticipated by Fearon, which the examiner believes discloses isolated complement receptor 1, and rejected claims 48-50 as obvious over Fearon in view of Capon. Fearon was applied as before, and Capon was cited for disclosing chimeric proteins

Serial No. 09/142,043

comprising a ligand binding partner fused to a plasma protein. Applicants respectfully traverse these rejections.

At the outset, applicants note that in order to reject a claim under 35 USC § 102, the examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986); *see also* MPEP § 2131 (Rev. 1, February 2000). Not only must the claim limitations be present, an allegedly anticipatory reference must enable the person of ordinary skill to practice the invention as claimed. Otherwise, the invention cannot be said to have been already within the public's possession, which is required for anticipation. *See Akzo, N.V. v. U.S.I.T.C.*, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986); *In re Brown*, 141 USPQ 245, 249 (CCPA 1964).

Similarly, the examiner must show all of the recited claim elements in the combination of references that make up the rejection. When combining references to make out a *prima facie* case of obviousness, the examiner is obliged to show by citation to specific evidence in the cited references that (i) there was a suggestion to make the combination and (ii) there was a reasonable expectation that the combination would succeed. Both the suggestion and reasonable expectation must be found within the prior art, and not be gleaned from applicants' disclosure. *In re Vaeck*, 20 USPQ2d

1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988); *see also* MPEP §§ 2142-43 (Rev. 1, February 2000).

When an examiner alleges a *prima facie* case of obviousness, such an allegation can be overcome by showing that (i) there are elements not contained in the references or within the general skill in the art, (ii) the combination is improper (for example, there is a teaching away or no reasonable expectation of success) and/or (iii) objective indicia of patentability exist (for example, unexpected results). *See U.S. v. Adams*, 383 U.S. 39, 51-52 (1966); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923, 1927 (Fed. Cir. 1990); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 230 USPQ 416, 419-20 (Fed. Cir. 1986). Applicants discuss the rejections with these concepts in mind.

Turning first to the anticipation rejection, the examiner has not shown that the sequence or size recitations of the claims are disclosed by Fearon. Accordingly, the examiner has not satisfied the burden of showing that each and every recitation is met by Fearon, and therefore the rejection should be withdrawn.

With regard to the obvious rejection, Capon does not rectify the deficiencies of the Fearon reference in any meaningful way. Thus, there is nothing in the combination of references that discloses or suggests the sequence or size recitations of the claims, and therefore the rejection should be withdrawn. Moreover, the examiner has pointed

Serial No. 09/142,043

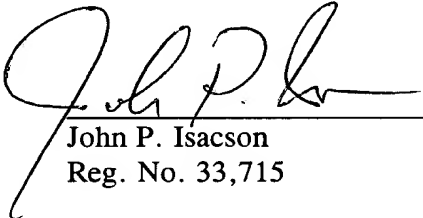
to no motivation emanating from the reference or the art to combine Fearon with Capon, which is another factor supporting withdrawal of the rejection.

Request

Applicants submit that the claims are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 672-5300 should there be any questions.

Respectfully submitted,

October 26, 2000



John P. Isacson
Reg. No. 33,715

FOLEY & LARDNER
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5109
Phone: (202) 672-5300
Fax: (202) 672-5399